

K 960269

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Attachment VII: Summary of Safety and Effectiveness Information [510(k) Summary]

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Synthes Ti Universal Clamp is compared to Synthes Double Adjustable Clamp.

Synthes Ti Universal Clamp is intended for use in the construction of an external fixation frame for the treatment of long bone fractures that require external fixation. The clamps attach the Schanz screws (pins) to an 11 mm carbon fiber rod or stainless steel tube. The Ti Universal Clamp is available in 2 sizes: four and six possible pin positions, which allow variable pin spreads in a two pin model. The device is manufactured from a Titanium Alloy.

Synthes Double Adjustable Clamp is intended for use in the construction of an external fixation frame for the treatment of long bone fractures that require external fixation. The clamps attach the Schanz screws (pins) to a carbon fiber rod or stainless steel tube. The Double Adjustable Clamp has three possible pin positions, to allow variable pin spreads in a two pin model. The device is manufactured from stainless steel.

Based on mechanical test results, the Ti Universal Clamp has been found to be substantially equivalent to the Double Adjustable Clamp.